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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,966	09/16/2005	Damian Joseph Peter Bond	13395.1001	6951

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EXAMINER	
DAMRON, ANITA B	

ART UNIT	PAPER NUMBER
4112	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,966	BOND ET AL.	
	Examiner	Art Unit	
	ANITA DAMRON	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/16/05* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office Action based on the 10/549,966 application filed September 16, 2005.

2. Claims 1-17 are pending and have been fully considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p) (4) because reference character "113" has been used to designate both dimples and LCD device. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: arrangement of specification is lacking subtitles.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

5. Claim 1 objected to because of the following informalities: "~~a~~" needs to be removed from section (a) of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, and 7-8 and 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by MINTER et al. (WO 00/33063).

7. Regarding Claim 1, MINTER et al. teaches **a sample testing device for testing for the presence of a component of interest in a liquid sample** *(determining the presence of a species in a liquid sample)* in the specification page 1 paragraph 1**, the device comprising:**

a. **at least one test capillary tube which has an upstream end and a downstream end and which incorporates an agglutination reagent system capable of causing agglutination with said component to be detected** *(a substrate along which a liquid may travel by capillary action) in the abstract (57) and (in accordance with a preferred embodiment of the invention is incorporated into a casing 11)* in the specification page 10 paragraph 1 and *(analyte binding to a reagent specific for that analyte is measured)* in the specification page 5 paragraph 6, indicating agglutination.

b. **a sampling region to which the liquid sample is applied and from which the sample is able to enter the upstream ends of the test capillary(s)** *(a sample application region in fluid communication with the liquid travel track(s))* in the specification page 3 paragraph 4.

c. **a power source** *(an electrochemical sensor that has its own integral power source.)* in the specification page 2 paragraph 1.

d. **a detection arrangement electrically associated with said power source for detecting the presence of liquid at a downstream region of said testing capillary** *(an electrochemical sensor that has its own integral power source. When liquid is applied to*

the sensor it will tend to be drawn along the substrate by capillary action) in the specification page 2 paragraph 1**;**

e. **display means operated by said power source for indication the result of the test** *(the electrochemical sensor may further comprise indicator means to display test results)* in the specification page 3 paragraph 6**; and**

f. **signal processing means associated with power source, detection arrangement and display means for evaluating the result of the test and providing said result of the test and providing said result on the display means** *(the indicator means incorporates an electronic circuit that interprets the output of the electrochemical detection arrangement and provides a specific signal at the indicator means depending upon the test results)* in the specification page 3 paragraph 6.

8. Regarding Claim 2, **device as claimed in claim 1, wherein the power source comprises electrodes of dissimilar metals provided at the sampling region of the device, said electrodes being adapted to generate a current when liquid sample is applied to said region** *(the electrodes of one material are interdigitated with those electrodes of another dissimilar material such that current, in the presence of liquid, may flow from one electrode to another)* in the specification page 2 paragraph 3.

9. Regarding Claim 3, **a device as claimed in claim 2, wherein the electrodes of the dissimilar metals alternate with each other** *(the electrodes are made of dissimilar metals and a most preferred arrangement has alternating copper and zinc electrodes)* in the specification page 2 paragraph 2.

10. Regarding Claim 4, **a device as claimed in claim 1, wherein the signal processing means incorporates a timing arrangement which is initiated by application of the liquid sample to the sampling region and wherein detection for the presence of liquid at the downstream region of the test capillary is effected within a predetermined time as governed by the timing arrangement.** *(the indicator means incorporates an electronic circuit that interprets the output of the electrochemical detection arrangement and provides a specific signal at the indicator means depending upon the test results)* in the specification page 3 paragraph 6 and *(it is preferable that the flow rate of the sample through the carrier should be at a rate of 1 cm in not more than 2 minutes but slower flow rates may be used if desired)* in the specification page 7 paragraph 5.

11. Regarding Claims 7-8 , MINTER et al. teaches **binding partner for said component immobilized on the walls of the test capillary** *(region 14 is printed with a specific anti-analyte antibody)* in the specification page 10 paragraph 4 and figure 3.

12. Regarding Claim 12, MINTER et al teaches **the detection arrangement comprises a pair of electrodes across which a potential difference may be applied** *(a pair of detection electrodes 9 capable of detecting electrochemically detectable species)* in the specification page 9 paragraph 2.

13. Regarding Claim 17, MINTER et al. teaches **at least one control capillary tube having an upstream end of the control capillary from the sampling region and the detection arrangement detects the presence of liquid at a downstream region of the control capillary** *(a third travel track may be provided to act as a control)* in the specification page 3

paragraph 5 and *(a third region 16, each region extending across the entire width of the assay track 5)* in the specification page 10 paragraph 4 and figure 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 5-6, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over MINTER et al. (WO 00/33063) in view of PRONOVOST et al. (US 5,786,220).

15. Regarding Claim 5, MINTER et al. teaches **agglutination reagent system** *(a substrate along which a liquid may travel by capillary action) in the abstract (57) and in accordance with a preferred embodiment of the invention is incorporated into a casing 11)* in the specification page 10 paragraph 1.

However MINTER et al. does not teach an agglutination reagent system comprising beads.

PRONOVOST et al. however teaches **agglutination reagent system comprising beads on which is immobilized a binding partner** *(blue latex beads coated with anti-hCG antibody)* in the specification column 10 line 45.

It would have been obvious to one with ordinary skill in the art to combine MINTER et al. binding partner with PRONOVOST et al. latex beads coated with anti-hCG antibody. Substrates commonly known in the art can comprise polymers and inert materials which can be in bead form, as well as other materials in micelle form, micelles carrying both markers binding partners. Both MINTER and PRONOVOST are assay systems involving the agglutination of hCG.

16. Regarding Claim 6, PRONOVOST et al. teaches **binding partner is an antibody** *(blue latex beads coated with anti-hCG antibody)* in the specification column 10 line 45.

17. Regarding Claim 9, MINTER et al. teaches **an agglutination reagent system** *(analyte binding to a reagent specific for that analyte is measured)* in the specification page 5 paragraph 6.

However, MINTER et al. does not teach agglutination in the presence of hCG.

PRONOVOST et al. however teaches **agglutination reagent system is capable of causing agglutination in the presence of hCG** *(a capture zone in the capture region is prepared by applying anti-hCG antibody along a first line)* in the specification column 10 lines 49-50.

It would have been obvious to one of ordinary skill in the art to combine MINTER et al. agglutination reagent system with PRONOVOST et al. agglutination in the presence of hCG to perform the desired test.

18. Regarding Claim 10, MINTER et al. teaches a preferred embodiment of the invention is incorporated into a casing 11.

However, MINTER et al. does not specifically teach a plate and lid arrangement.

PRONOVOST et al. teaches **capillary is formed by a co-operating plate and lid arrangement, said plate being formed with channels which become capillary tubes on location of the lid** *(a first surface 12 and a parallel second surface 14 one of which has channels 16 formed therein such that when two surfaces are placed together a chamber or microchamber 18 is formed through which liquid will flow by capillary action)* in the specification page 3 lines 14-17.

It would have been obvious to one with ordinary skill in the art to combine MINTER et al. casing with PRONOVOST et al. first surface and second surface to illustrate the plate and lid arrangement of creating capillary tubes.

19. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over MINTER et al. (WO 00/33063) view of PRONOVOST et al. (US 5,786,220), in further view of PARSONS et al. (EP 0 321 736 A2).

20. Regarding Claim 11, **MINTER** et al. teaches **downstream regions of the test capillary tube have at least one aperture and the detection arrangement is provided beneath said aperture** *(can electrochemical sensor in accordance with a preferred embodiment of the invention is incorporated into a casing 11 which has an aperture 12 above the sample application region 2 and an aperture 13 above the indicator means 10)* in the specification page 10 paragraph 1.

21. Claims 13-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over MINTER et al. (WO 00/33063) in view of PARSONS et al. (EP 0 321 736 A2).

22. Regarding Claim 13, MINTER et al teaches a test capillary *(a substrate along which a liquid may travel by capillary action) in the abstract (57) and in accordance with a preferred embodiment of the invention is incorporated into a casing 11)* in the specification page 10 paragraph 1.

However MINTER does not teach a particulate material to enhance the change in flow rate.

PARSONS et al. however teaches a **test capillary** that **incorporates a particulate material to enhance the change in flow rate** *(various means for controlling the flow of sample through the capillary chambers 18 in order to properly perform the agglutination reaction are also provided. One method is to place a water-soluble material, such as a water-soluble polymer, in at least a portion of the channels that will be resolubilized by the application of a sample material)* in the specification page 3 lines 39-42.

It would have been obvious to one with ordinary skill in the art to combine MINTER et al. test capillary with PARSONS et al. test capillary incorporating a particulate material to

enhance the flow rate. Incorporating materials to line a flow path is commonly known in the art. This is done for filtering, and adding a swellable material would reduce the flow path diameter, changing the flow rate.

23. Regarding Claim 14, PARSONS et al. teaches **said material is an inert particulate material** *(example of water-soluble substances can include polyvinylpyrrolidone (PVP)* in the specification page 3 line 42. One of ordinary skill in the art would know that PVP is inert.

24. Regarding Claim 16, MINTER et al. teaches **particulate material is a swellable polymer** *(nitro-cellulose as the substrate)* in the specification page 7 column 4.

25. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over MINTER et al. (WO 00/33063) in view of PARSONS et al. (EP 0 321 736 A2), in further view of ALCOCK et al. (US 5,736,188).

26. Regarding Claim 15, MINTER et al. teaches **particulate material** *(nitro-cellulose as the substrate)* in the specification page 7 column 4.

PRONOVOST et al. teaches a matrix of latex beads in the specification column 10 line 45.

However MINTER et al. and PRONOVOST et al. do not teach silica or bentonite.

ALCOCK et al. however teaches **an inert particulate material silica or bentonite** *(silica gel)* in the specification column 4 line 45.

It would have been obvious to one of ordinary skill in the art to combine MINTER et al. nitro-cellulose substrate with PRONOVOST et al. matrix of latex beads with ALCOCK et al. silica gel as the substrate for retention of the reagent. These are all substrate materials

commonly used in the art, in addition, MINTER et al., PRONOVOST et al., and ALCOCK et al. all teach printed fluid transport devices.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure ***DURST et al. (US 5,756,362), and WOHLSTADTER et al. (US 6,673,533 B1) all involve fluid testing similar to the invention*** is related to the main reference cited in this action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANITA DAMRON whose telephone number is (571)270-5549. The examiner can normally be reached on Monday through Thursday 7:30 to 5:00 every other Friday 7:30 to 4:30.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara L. Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anita Bucsay Damron

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